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EXAMINER
FORMAN, BETTY J

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	**Application No.** 10/681,630	**Applicant(s)** DAVIS, RANDALL W.
	Examiner BJ Forman	**Art Unit** 1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2006*.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.
  4a) Of the above claim(s) *22-34* is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-21,35 and 36* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on *08 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.
  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  a)☐ All b)☐ Some * c)☐ None of:
    1.☐ Certified copies of the priority documents have been received.
    2.☐ Certified copies of the priority documents have been received in Application No. _____.
    3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
  * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, Claims 1-21, 35-36 in the reply filed on 11 April 2006 is acknowledged. The traversal is on the grounds that it would not be undue burden to examine the claims of all groups I and II. However, it is maintained that undue burden would be required to examine the claims of group II along with claims of group I as evidenced by the fact that the claims of groups I and II have acquired a separate status in the art as recognized by their different classifications as recognized by their divergent subject matter and because a search of the subject matter of invention I is not co-extensive with a search of invention II.

The requirement is still deemed proper and is therefore made FINAL.

Claims 22-34 are withdrawn.

Claims 1-21 and 35-36 are under prosecution.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested:

Semiconductor Apparatus for Identification of Biomolecules

Drawings

3. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because figures 1 and 3-14 are not identified as "Prior Art" as described in the Brief

Description of the Drawings.. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-21, 35-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-21, 35-36 are indefinite in Claim 1, lines 12 and 14-15 for the recitation "the sense site gap" because the recitation lacks proper antecedent basis in the claim.

Claim 15 is indefinite for the recitation "the array/sense site" because the recitation lacks proper antecedent basis in Claim 1.

Regarding Claim 20, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 21 is indefinite because the claim is drawn to a matrix of closed sites but further defines the substrate manufacture during which the sites are opened. It is unclear whether the claim is defines the apparatus having closed or open sites. It is suggested that the claim be amended to clarify.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 4-10, 13-14, 17-18, 20-21and 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Eichen et al (WO 99/57550, published 11 November 1999).

Regarding Claim 1, Eichen et al disclose a semiconductor substrate having a top side, a bottom side (page 17, lines 3-13, page 37, lines 14-20 and Fig 33-35) and external electrical contacts (page 6, lines 24-28), the apparatus comprising a plurality of sense site within the top surface defining a matrix (Fig. 33-35) wherein each site comprises a four-sided well constructed of silicon dioxide insulating layers (page 17, lines 3-13, page 61, lines 19-25 and Fig. 33-35), a gap to receive probe molecules, a gap capable of changing resistivity (page 23, lines 6-11), means to affix probe molecules in the sense gap (e.g. linkers, Example 1, page 33, line 20-page 34, line 23), means to electrically detect biomolecules within the gap (conductive bridge formed between the electrodes (page 5, line 21-page 6, line 28), means to vary resistivity across sense site (i.e. bridge formation (page 8, lines 3-16 and Fig. 20) and means to break surface tension of liquids (e.g. micropipette or ink jet delivery of droplets, wherein droplets are formed by breaking away from the liquid dispensers (Example 2, page 34-35), means to control semiconductor substrate temperature (page 49, lines 25-28), means to protect the top side (#1010, Fig. 37 and Example 29) means to sequentially read parallel electrical measurements from multiple sites (Examples 27-28, especially page 60, line 18-page 61, line 5) means to separate a sample applied to gaps (e.g. gap walls formed by cutting out portions of the substrate, page 17, lines 3-13 and/or electric field for directing charged moiety, page 12, lines 1-7) and means to separate a sample into multiple separate sense sites (e.g. micropipette or ink jet delivery of droplets, Example 2, page 34-35 and/or reservoirs in the chip base as illustrate by arrows in Fig. 37, page 62, lines 23-27).

Regarding Claim 2, Eichen et al disclose the apparatus wherein the substrate is silicon (page 37, lines 14-20).

Regarding Claim 4, Eichen et al disclose the apparatus wherein the means for affixing probes comprises a bioreactive material comprising carbon and/or hydrophilic organic polymers (e.g. thiophosphate containing nucleotides, page 34, lines 15-19).

Regarding Claim 5, Eichen et al disclose the apparatus wherein the substrate further comprise a diode or unidirectional semiconductor device (page 16, lines 5-16).

Regarding Claim 6, Eichen et al disclose the apparatus wherein the gap comprises two conductive traces on opposite sides of the same gap (page 17, lines 3-13) wherein the variable resistance gap substrate separates and is connected to the conductive traces (page 61, lines 8-28) wherein the sense sites form a matrix and is addressable and readable (Examples 27-28, especially page 60, line 18-page 61, line 5). The claim recites numerous elements used with apparatus of claim 1 e.g. microprocessor, multiplexer, amplifier circuits etc. However the claim does not define the apparatus as comprising these elements. It is noted that Eichen teaches the detection sites of apparatus are individually controllable and detectable (Examples 27-30) and use of the recited devices. However, the apparatus of Claim 6, as written is not limited to the recited microprocessor, multiplexer, amplifier circuits etc.

Regarding Claim 7, Eichen et al disclose the apparatus wherein the means for affixing the probe comprises a functionalized reagent (e.g. linker, Example 1, page 33, line 20-page 34, line 23).

Regarding Claim 8, Eichen et al disclose the apparatus wherein the top surface of the substrate is coated with a passivation layer (Examples 5 and 19).

Regarding Claim 9, Eichen et al disclose the apparatus of Claim 1 as discussed above and further teach the apparatus further comprises means for applying a magnetic field (page

51, line 30) for moving metallic particles forming the nucleation center (Fig. 30 and page 6, lines 5-15 and page 57, lines 10-22).

Regarding Claim 10, Eichen et al disclose the apparatus wherein the means to break surface tension comprises a liquid shunt (e.g. electric field for directing charged target to a recognition moiety, page 12, lines 1-7).

Regarding Claim 13, Eichen et al disclose the apparatus wherein the substrate comprises non-oxidized material e.g. silica (Example 4, page 37, lines 14-20).

Regarding Claim 14, Eichen et al disclose the apparatus wherein the means for sequentially reading multiple sites comprises a portable instrument (e.g. computer and/or software, page 61, lines 3-5).

Regarding Claim 17, Eichen et al disclose the apparatus wherein center-to-center spacing of the sense sites is not more than 50 microns (Fig. 34).

Regarding Claim 18, Eichen et al disclose the apparatus wherein three neighboring site contain the same sample (e.g. 100 detection sites/hybridization sites, page 60, lines 12-17 and Fig. 33) and wherein each site is independently addressed for analysis (page 60, line 18-page 61, line 5).

Regarding Claim 20, Eichen et al disclose the apparatus comprising a temperature sensitive element to determine and control substrate temperature (i.e. temperature control apparatus to control and modify temperature automatically, page 49, lines 26-28).

Regarding Claim 21, Eichen et al disclose the substrate having initially closed sites which during apparatus construction are opened using laser techniques (page 38, lines 1-11) and wherein the substrate of the apparatus further comprise a diode or unidirectional semiconductor device (page 16, lines 5-16).

Regarding Claim 35, Eichen et al disclose the substrate comprise various (i.e. multiple) resistive sense sites (Examples 27-30 and Fig. 33-36).

Regarding Claim 36, Eichen et al disclose the substrate comprise a family of various resistive sense sites (e.g. 100 detection sites/hybridization sites, page 60, lines 12-17 and Fig. 33).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 3 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eichen et al (WO 99/57550, published 11 November 1999) in view of Yager et al (U.S. Patent No. 6,176,990, issued 23 January 2001).

Regarding Claims 3 and 15, Eichen et al disclose the apparatus of Claim 1 as discussed above and further teach the semiconductor substrate is made of "any other substance capable of acting as a support" e.g. silicon (page 37, lines 14-19) but they do not teach the substrate is germanium. However, germanium was known in the art as a functional equivalent to the silicon substrate as taught by Yager et al.

Yager et al teach a similar apparatus comprising a semiconductor substrate, reaction site matrix, a temperature control device and means to sequentially read and analyze the sample (Column 3, lines 50-60; Column 4, lines 47-67; Column 5, lines 32-35) wherein the substrate is germanium (Column 4, lines 48-50) and further wherein the apparatus comprises a portable analysis instrument comprising a chamber to perform liquid processing of the sample wherein the sample is read the measurements are transmitted (Fig. 6 and 8). The sample is processed onto a sequencing chip which is then inserted into an analysis device

(Column 8, lines 18-20, and line 64-Column 9, line 19). Yager et al teaches the advantage of providing the independent instrument is that is separates the inexpensive sequencing chip from the expensive detection system (Column 9, lines 16-19).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the analysis instrument of Yager et al to the apparatus of Eichen et al for the benefit of separating the inexpensive sequencing chip from the expensive detection system as desired in the art, Yager et al (Column 9, lines 16-19).

10. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eichen et al (WO 99/57550, published 11 November 1999).

Regarding Claim 12, Eichen et al disclose the apparatus of Claim 1 as discussed above comprising electrode sites but the reference is silent regarding the shape of the electrodes.

However, the courts have stated that absent evidence to the contrary, a particular configuration of a known device is a matter of choice which would have been obvious to one skilled in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.). Therefore, the claimed rounded edges would have been an obvious variation of the electrodes of Eichen et al.

11. Claims 11, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eichen et al (WO 99/57550, published 11 November 1999) in view of Nielson et al (U.S. Patent No. 6,236,088 issued 22 May 2001).

Regarding Claims 11, 16 and 19, Eichen et al disclose the apparatus of Claim 1 as discussed above and further teach the apparatus comprising a temperature sensitive element to determine and control substrate temperature (i.e. temperature control apparatus to control and modify temperature automatically, page 49, lines 26-28) but they do not teach a circuit that allows resistance to be adjusted, a comparator circuit or a temperature sensitive diode. However, semiconductor electrode substrates comprising these elements were well known in the art at the time the claimed invention was made as taught by Nielson et al. (Column 2, lines 13-24). Neilson et al teach the apparatus comprising the diode and circuits (Column 6,lines 32- Column 7, line 64) and further teach their function suppresses localized hot spots while allowing continued use of the device. Nielson et al teach that localized hot spots tend to attract even higher current densities and even higher temperature leading to damage of the device (Column 4, lines 10-17). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the diode and circuit of Nielson et al to the substrate of Eichen et al for the expected benefit of suppressing localized hot spots and preventing damage while continuing use of the device as taught by Nielson et al (Column 4, lines 10-17).

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
June 16, 2006